In re application Bertucci and Felix

U.S. National Phase Application

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Amendments to the Claims

Please Cancel Claims 1 to 11 without prejudice.

Based on Intl. Application No. PCT/GB03/00119

12. (Currently amended) A method process for selecting an enantiomer of a chiral

compound, comprising the steps of

(i) exposing a mixture of enantiomers of the compound to highly homogenous

serum albumin for a period to allow selective binding of one enantiomer to the

albumin; and

(ii) separating the relatively unbound enantiomer from the albumin.

13. (Currently amended) The method A process according to Claim 12 wherein the

highly homogeneous serum albumin is immobilised.

14. (Currently amended) The method A process according to Claim 13 wherein the

immobilised highly homogeneous serum albumin is immobilised on an enantioselective

chromatography column as defined in any one of Claims 8 to 10.

15. (Currently amended) The method A process according to any one of Claims

Claim 12 to 14 further comprising the step of separating the relatively bound enantiomer

from the albumin.

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16. (Currently amended) The method A process according to any one of Claims

Claim 12 to 15 wherein the chiral compound is selected from an amino acid, an amino

acid derivative, a sulfoxide, a sulfoxamine derivative, a racemic amine, a non-steroidal

anti-inflammatory drug, an aryl propionate anti-inflammatory drug, an N-methylated

barbiturate a benzodiazepine, a profen and a coumarin.

17. (Currently amended) The method A process according to any one of Claims Claim

12 to 16 wherein the chiral compound is selected from warfarin, warfarin metabolites

such as 6- and 7-hydroxywarfarin and warfarin alcohols, lorazepam (e.g. lorazepam

hemisuccinate), oxazepam, temazepam, N-benzoyl-DL-leucine, tryptophan, benzoin,

eprisone, chlorphemramine, kynurenine, prilocaine, promethazine, donepezil and its salts

(e.g. donepezil hydrochloride, sold under the trade name Asicept), thiopenfal, ibuprofen,

naproxen, ketoprofen, suprofen or fenoprofen and salts of these.

18. (Currently amended) A method process for increasing the purity of an agent that

binds to albumin, comprising the steps of

(i) exposing a relatively impure preparation of the agent to an affinity

chromatography column comprising, in the immobilised phase, highly homogeneous

serum albumin, under conditions that favour the selective binding of the agent to the

albumin;

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(ii) removing unbound components of the relatively impure preparation of the

agent; and

(iii) eluting the agent from the affinity chromatography column to obtain a

preparation of the agent with increased purity.

19. (Currently amended) The method A process according to any one of Claims Claim

12 to 18 further comprising the step of formulating a the thus separated enantiomer or

agent with increased purity with a pharmaceutically acceptable carrier or diluent, thereby

to produce a pharmaceutical preparation.

20. (Currently amended) The method A process according to Claim 17 further

comprising the step of presenting the pharmaceutical preparation in a unit dosage form.

21. (Currently amended) The A use, an enantioselective chromatography column, or

a method process according to Claim 12 any one of the preceding claims wherein the

highly homogeneous serum albumin is highly homogeneous human serum albumin.

22. (Currently amended) The A use, an enantioselective chromatography column, or

a method process according to Claim 12 any one of the preceding claims wherein the

highly homogeneous serum albumin is highly homogeneous recombinant serum albumin.

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23. (Currently amended) An enantiomer of a chiral compound obtainable by a method

according to any one of Claim 12 to 17.

24. (Currently amended) A use, an enantioselective chromatography column, or a

method process substantially as described herein with reference to the examples.

25. (New) The method of Claim 14 wherein the enantioselective chromatography

column comprises an immobilised phase comprising highly homogeneous serum

albumin.

26. (New) The method of Claim 14 wherein the enantioselective chromatography

column is used for HPLC.

27. (New) The method of Claim 14 wherein the enantioselective chromatography

column comprises highly homogeneous serum albumin immobilised on a silica matrix.